



Editorial: AI has sprung

Beautiful flowers – and annoying weeds – pop up everywhere at Springtime, in the same way that AI has sprung into our lives. Once just two vowels in the Roman alphabet, this mighty combination is now wreaking havoc, notably on the job markets. 'AI is making it harder for young people to land jobs in law'. So said former British Prime Minister Rishi Sunak back in February, at the AI Impact

Summit in New Delhi. Other white-collar professions have also largely suspended recruitment, waiting to see whether they can indeed dispense with the human factor as AI's abilities seem to grow exponentially.

This latest technology driven revolution is not only affecting employment. In its 2022 report, the OECD first applauds how the extensive efficiency gains driven by AI are helping us to reach net-zero targets, before underlining its direct negative impact on resource consumption, specifically water. On the other hand,

Chief Economist Robert Staiger highlighted on the WTO blog that much of last year's 4.6% expansion in world merchandise trade volumes came from the 'AI surge': booming investment in data centres, processors, semiconductor equipment and other AI-enabling products.

Perhaps this contradiction can be resolved by human creativity. New research led by Cambridge University has revealed that creating human brain-inspired computing is an alternative way to process information that could ultimately reduce energy use by as much as 70%. By mimicking the brain, and storing and processing information in the same place, the current movement of data that consumes vast amounts of electricity could be massively reduced.

In the meantime, your Editor continues to write without the use of AI, surrounded by the beauty of Nature as a source of inspiration. I cherish the fact that I have the time to do so.

Vanessa

US Update: A Rose by Any Other Name

Kathryn Eyster, Tepper & Eyster

The USPTO's doctrine of foreign equivalents holds that, if a party seeks to register a trade mark which contains a word in a foreign language, registrability should be determined by considering the English translation of that word. For example, if 'beer' is descriptive of your goods when written in English, it is still descriptive of those goods if you instead call it 'cerveza.' There seems to be little doubt that a foreign word should only be translated if it is likely that an American consumer would stop and translate that word. However, in the case of lesser-known languages, there is room for dispute over whether the typical American consumer would indeed do so.

In the case *In re Helande, LLC* (TTAB Feb. 13, 2026) [not precedential], the Trademark Trial and Appeal Board had to determine whether the proposed mark HELANDE was descriptive for medicated and non-medicated skin care preparations. For those who do not speak Swedish, the Swedish translation of HELANDE is 'healing.' Invoking the doctrine of foreign equivalents, the examining attorney refused registration, finding that 'healing' is merely descriptive for skin care preparations. The Applicant didn't dispute that 'healing' was descriptive but instead argued that the doctrine of foreign

equivalents should not be applied to this case.

The Federal Circuit, the primary court reviewing decisions of the TTAB, has provided guiding principles for analyzing these cases. A word should be translated if 'an appreciable number' of consumers 'with ordinary sensibilities' would likely stop and translate the word. See *In re Vetements Grp. AG*, 137 F.4th 1317, 1331 (Fed. Cir. 2025). The burden of proof is on the party who opposes translation. The Federal Circuit has also found that the 'ordinary American purchaser' includes purchasers who are proficient in other languages. See *In re Spirits Int'l, N.V.*, 563 F.3d 1347, 1352 (Fed. Cir. 2009).

It is important to note that the application for HELANDE included a statement that the word meant 'healing' in Swedish. The Applicant also failed to provide evidence of any contradictory or indefinite definitions of the word. On appeal, the Applicant argued that 'healing' was not a literal translation because 'helande' could also mean 'curative' and because it was a form of the word 'hela,' which has several meanings. However, the Board did not find 'curative' to be a conflicting meaning and did not care about other versions of the word. The Board also noted that the Applicant had a statement on its website

indicating that its products were influenced by the Swedish concept of healing. Therefore, the Applicant's primary argument was that Americans would not translate its mark at all because Swedish is not in a 'common, modern language' in the US.

The Board found that the test is not whether citizens view Swedish as a common, modern language. Instead, the test is whether the language is one of the modern languages of a principal nation and whether an 'appreciable number of Americans' can translate the term. Finding that there are millions of people in the world who speak Swedish and that Sweden is a principal nation with the largest Nordic economy, the Board quickly deemed the first portion of the test met. The more complicated issue was whether an appreciable number of American citizens would translate the Swedish word, and the burden was on the Applicant to show why the term should not be translated.

The Applicant provided testimony from the Executive Director of the American Swedish Historical Museum in Philadelphia, who believed the language to be rare.

continued on page 4

Words from the Chair



As we move further into the year, it is a pleasure to reflect on the strength and momentum of our community. Our recent conference in Munich was a real success, bringing together colleagues and friends for excellent presentations, thoughtful discussions and perhaps most importantly, the opportunity to reconnect. The energy throughout the conference was a timely reminder of the value of coming together to exchange ideas, share experience and strengthen the professional ties that underpin our group.

Looking ahead, I know that everyone has been waiting to hear about our location for the Autumn conference. We are disappointed not to be able to go to Oman this year but we hope to be there for the next Autumn conference and our thoughts are with everyone in the region.

I am very pleased to announce the location of our Autumn conference, which will take place in Prague in the Czech Republic from 7th to 10th October 2026. Prague is a city with a rich history, striking architecture and a vibrant cultural life and I am sure it will provide an inspiring setting for what promises to be another memorable PTMG conference.

I would like to take this opportunity to thank Lesley for all the hard work that has gone into finding an alternative location. I hope many of you will be able to join us there as we look ahead to the opportunities and challenges still to come.

Best wishes

Joanne

Obituary: Dr. Peter Dirk Siemsen

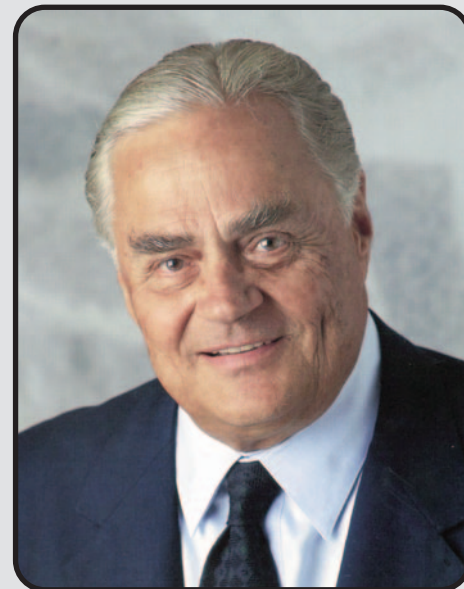
PTMG is deeply saddened by the recent loss of one of its charismatic members Dr. Peter Dirk Siemsen. Peter was an IP legend and of course a former partner at the Dannemann Siemsen firm, which he joined in 1947. Peter was not only instrumental in Brazil as he co-founded the Brazilian Intellectual Property Association (ABPI) in 1963, but also within the whole American continent with his participation in the foundation of ASIPI (Inter-American Association of Intellectual Property) in 1964. He received many international accolades and had several leadership roles in leading IP associations. His footprint expanded well beyond IP to reach sports, and in particular sailing. Peter was not only passionate about sailing; he was actually an incredible sailor! Peter has been Brazilian and South American champion! He has also been an arbitrator at the Court of Arbitration for Sport and served as an international and Olympic sailing judge.

I will remember Peter as an outstanding IP architect who leaves a significant legacy, a reputed sports character but above all someone who enjoyed his life and family very much - he was always smiling, ready for a dance and with a contagious happiness. We will miss him very much and we extend our sincere condolences to his family, friends and colleagues at the Dannemann Siemsen law firm.

David Lossignol Novartis

Meeting Peter

Peter was my first boss, and an influential figure in my professional life. Many people in the international intellectual property (IP) community have met him over the many decades he was active worldwide. From the age of twenty-two, I found myself in awe of him. At that time, I was a young Brazilian lawyer beginning my career during a period when very little seemed to function in Brazil - politics, the economy, and society were all in disarray. Life felt chaotic and uncertain. Yet, I found myself employed in a place where everything worked efficiently, and the driving force behind that remarkable environment was a man with a clear sense of direction. Peter managed to establish himself and his firm on the international stage in such an extraordinary way that only those who experienced those days can truly appreciate the magnitude of his achievements.



A Pivotal Lesson

One day, Peter summoned me to his imposing office, which was dominated by a massive table crafted from an enormous tree. It was an intimidating setting, and he called me there to reprimand me. I had filed numerous trade marks for a large client, not because they were necessary, but because I lacked the courage to advise the client otherwise. The trade marks were borderline in terms of distinctiveness, and I was hesitant to make the decision to recommend against filing them. I had no clear strategic approach; instead, I simply covered all possible bases, and the client paid for it. During our meeting, Peter taught me that there is often no definitive right answer in situations like this. However, it is essential to always provide your best answer, even when it is not the easiest or safest choice. He essentially told me that I needed to learn to 'make the call'.

Applying the Lesson and Passing It On

A couple of years after that formative encounter, I left Brazil and transitioned to an in-house position. The lesson Peter imparted proved fundamental to my in-house career, where legal advice and business decisions are closely intertwined. Making legally sound and business-oriented decisions is what distinguishes a good in-house counsel. Over the past thirty-plus years since that memorable meeting, I have shared Peter's message with several generations of lawyers who have worked with me. This is Peter's legacy in my life and in the lives of many other lawyers.

Maria Fernandez Marques Novartis

Members News

New Members

We are delighted to welcome the following new members to the Group:

Laura Nend from Lewis Silkin LLP, London, UK laura.nend@lewissilkin.com

Marie Keup from Taylor Wessing, Brussels, Belgium
m.keup@taylorwessing.com

Adrianna Pilecka from CWMiP, Warsaw, Poland adrianna.pilecka@cwmipl.pl

Vintee Singh from Nestlé, Vevey, Switzerland vintee.sigh@nestle.com

Rainer Böhm from Eisenführ Speiser, Hamburg, Germany rbohm@eisenfuhr.com

Maya Muchemwa from Womble Bond Dickinson (UK) LLP, Leeds, West Yorkshire, UK maya.muchemwa@wbd-uk.com

Caroline von Nussbaum from Simmons & Simmons LLP, Munich, Germany
caroline.vonnussbaum@simmons-simmons.com

Pascal Böhner from Bardehle Pagenberg, Munich, Germany
pascal.boehner@bardehle.de

Beatrix Breitinger from Wuesthoff & Wuesthoff, Munich, Germany
breitinger@wuesthoff.de

Jason Joyal from Kelly IP LLP, Washington, DC, USA
jason.joyal@kelly-ip.com

Daniel Plane from East IP, Wanchai, Hong Kong
andyalcock@east-ip.com

Florian Manzenrieder from TBK, Munich, Germany manzenrieder@tbk.com

Alexandra Dellmeier from LexDellmeier, Munich, Germany
a.dellmeier@lexdellmeier.com

Saurabh Bhushan from P.S. Davar and Company, New Delhi, India
saurabh@psdavar.co.in

Angeline Lee from AWA, Causeway Bay, Hong Kong Angeline.lee@awa.com

Pourya Vatankhah from CSC Digital Brand Services, Frankfurt am Main, Germany
pourya.vatankhah@cscglobal.com

Jason Kasner from Lerner David LLP, Cranford, New Jersey, USA
jkasner@lernerdavid.com

Ketevan Weissflog from RWS, Starnberg, Germany kweissflog@rws.com

Lukas Bischoff l.bischoff@mb.de and **Tobias Popp** t.popp@mb.de both from Meissner Bolte, Munich, Germany

Laura Fernandez from Zacarias & Fernandez, Asuncion, Paraguay
l.fernandez@zafer.com.py

Vincent de Vos from Mintz Group (UK) Ltd, Worthing, East Sussex, UK
vdevos@mintzgroup.com

Philipp Strommer from Epic Legal, Munich, Germany
Philipp.strommer@epic.legal

Idalla Brum Pereira from Msantos Intellectual Property, Rio de Janeiro, Brazil
idalla.brum@msantosip.com

Isabella Buck Shores from Daniel Law, Rio de Janeiro, Brazil
isabella.shores@daniel-ip.com

Stefan Moritz from EBRAND, Leudelange, Luxembourg
smoritz@ebrand.com

Lucas Aebersold from Troller Hitz Troller, Bern, Switzerland
aerbersold@trollerlaw.ch

Ilse van Haaren from Clarivate, Lier, Belgium ilse.vanhaaren@clarivate.com

Colin Costello from GoDaddy Corporate Domains, Tempe, Arizona, USA
colin@gcd.com

Bernhard Pillep from Kador & Partner, Munich, Germany
bernhard.pillep@kadorpartner.com

Louise Foster from Venner Shipley LLP, London, UK lfoster@vennershipley.co.uk

Mohamed Adel Hussein from United Trademark and Patent Services, Cairo, Egypt adel@unitedtm.com

Moves and Mergers

Florencia Torresani has left ClarkeModet to join Ungria in Madrid, Spain. Florencia can be contacted at ftorresani@ungria.es

Graham Farrington has left Ladas & Parry LLP to join Abion UK Limited. Graham can now be contacted at graham.farrington@abion

Janhvi Chadha has left Krishna and Saurastri to join Fidus Law Chambers in Mumbai, India. Janhvi can be contacted at janhvi@fiduslawchambers.com

Larry Rickles has left Teva and is now with Moore & Van Allen in Charlotte, North Carolina, USA. Larry can be contacted at lrickles@mvalaw.com

Kristiane Vandborg has left H. Lundbeck A/S and joined Novo Nordisk in Bagsvaerd, Denmark. Kristiane can be contacted at kbqv@novonordisk.com

Tina Rees-Pedlar has left Bryers LLP to join Stevens Hewlett & Perkins in Bristol, UK. Tina can be contacted at trees-pedlar@shandp.com

Christian Bardenfleth has left Plesner Law Firm to return to Zacco Denmark A/S in Copenhagen, Denmark. Christian can be contacted at Christian.bardenfleth@zacco.com

Mark Peroff is now with Lerner David LLP in Cranford, New Jersey, USA and can be contacted at mperoff@lernerdavid.com

Maureen Daly has left Pinsent Masons Ireland LLP to join Reddy Charlton LLP in Dublin, Ireland. Maureen can now be contacted at mdaly@reddycharlton.ie

Julia Allen-Benecik has left Taylor Wessing Vienna and established her own firm, J.A. Legal, in Vienna, Austria. Julia can be contacted at office@ja-legal.at

Please remember to let us know of any changes to your contact details. You can notify me either via the PTMG website www.ptmg.org or directly to Lesley@ptmg.org or by writing to me at Tillingbourne House, 115 Gregories Road, Beaconsfield, Bucks, HP9 1HZ

Lesley Edwards
PTMG Secretary

US Update Cont

He noted that few students enrolled in the museum's Swedish language classes, and that the Swedish museum exhibits were labeled in English. Applicant also submitted a statement from the Program Manager of Swedish Language Studies of the Swedish Institute that only 23 out of thousands of universities in the United States teach Swedish. The Board did not find these statements, or 'personal opinions' to be persuasive evidence of anything other than the fact that Swedish is less common in the US than other languages.

As of 2022, only .02% of the American public (about 76,000 people) were Swedish speakers. However, the Board found that even small numbers of speakers can give rise to 'an appreciable number' of people who can translate a term. The Board noted that the doctrine has been applied to Greek and Japanese, even though there are not large numbers of Americans who speak those languages either. Further, the Applicant had provided no evidence that the term 'healing' was an obscure or technical term that required advanced knowledge of the Swedish language (prior decisions had found 'clothing' to be a common word but 'widow' to be more advanced). See *Vetements*, 137 F.4th 1317. In a last-ditch effort, the Applicant argued that a third party had attempted to register the mark HELANDE INNOVATIONS for spinal implants and was not asked to disclaim the term 'helande' as descriptive. The Board was not moved by a single prior decision by an examiner. While admitting that the Applicant was entitled to have any doubts resolved in its favor, the Board concluded that there were simply no doubts to resolve.

In this case, the Board was clearly influenced by the Applicant's own translation statement, by lack of evidence of any contrary meaning or evidence that the term was advanced, and by the Applicant's advertising references to Sweden. It is worth noting that a Board decision in 2024 found no appreciable number of consumers might translate a Lithuanian term where less than 40,000 people in the US spoke Lithuanian. In *re MJ Cobalt, LLC*, Serial No. 97673097 (May 9, 2024) [not precedential] the dissenting judge found that the number of speakers should only be relevant in cases involving confusingly similar marks, not as to the issue of descriptiveness or the validity of the mark at registration. However, where there are 76,000 Swedish speakers (and the right set of facts), an appreciable number of consumers can translate Swedish.

The takeaways from this case are to choose translation statements carefully before putting them in the trade mark record and to avoid making references to that translation on websites or marketing materials if it is in any way descriptive. A rose by any other name ... can still be descriptive.

German Supreme Court rules on perception of the trade mark H 15 in composite signs

Thomas Tresper, Tresper IP, Germany

In a recent decision concerning pharmaceutical trade marks, the German Supreme Court provided guidance on establishing genuine use and likelihood of confusion where the earlier mark is used in composite signs (decision of 20/11/2025, I ZB 30/25). https://www.bundesgerichtshof.de/SharedDocs/Entscheidungen/DE/Zivilsenate/I_ZS/2025/I_ZB_30-25.pdf?__blob=publicationFile&v=1

Background

The appellant applied to register the German trade mark Hecht H 15 for food supplements in Class 5.

The respondent opposed based on an earlier German trade mark registration for H 15 covering, inter alia, pharmaceutical products in Class 5. When proof of use was requested, the respondent submitted evidence of the marketing in Germany of an anti-inflammatory Ayurvedic medicine under the name H 15 Gufic, for which it held a marketing authorisation in India, in the following forms:



The German Patent and Trade Mark Office upheld the opposition. The Federal Patent Court dismissed the appeal.

Decision

The Supreme Court upheld the appellant's further appeal and referred the case back to the Federal Patent Court. The Patent Court had found that the product H 15 Gufic had been sold to pharmacies and could be lawfully resold by them in Germany. The Supreme Court rejected the appellant's proposition that a pharmaceutical product should be classified as such only if, based on its composition, dosage form and functional purpose, it is suitable and intended for the treatment or prevention of disease. The definition of a medicinal product in Art. 1(2)(a) of Directive 2001/83 includes products that are presented as having properties for treating or preventing disease. Accordingly, the Patent Court was entitled to conclude that the relevant public, consisting of healthcare professionals and patients, perceived the product as a medicinal product, regardless of its objective properties. Further, the Supreme Court confirmed that the relevant public would perceive the combination H 15 Gufic as consisting of two separate signs, H 15 and Gufic. It was conceivable, however, that the public recognised only the sign Gufic as an indication of origin and did not regard the sign H 15 as a trade mark, but rather as a designation of the preparation within the

manufacturer's product range. The Patent Court had not established that there is a practice of naming medicinal products with abbreviations consisting of letters and numbers, nor that the relevant public recognises the use of such signs, in conjunction with a manufacturer's indication, as an indication of origin.

Should it be established that the sign H 15 is perceived as an independent indication of origin, then the Patent Court was correct to find a likelihood of confusion based on the earlier mark H 15 having an independent distinctive role in the composite sign Hecht H 15. From the case-law of the CJEU, it followed that the concept of an independent distinctive role could also be applied in cases where the goods or services are not identical but merely similar.

Comment

The attraction of this decision is that the earlier mark H 15 is included in composite signs that had to be assessed from different angles, namely, genuine use (in H 15 Gufic) and likelihood of confusion (in Hecht H 15).

At first glance, it might seem foolproof to request proof of use of a trade mark for a medicinal product that lacks regulatory approval in the relevant territory. The German courts, however, do not exclude the possibility of establishing genuine use in such cases (see LL&P May 2024, p. 6). It suffices if the product can be lawfully marketed and is perceived as a medicinal product by virtue of its presentation. The opponent's weak spot in proving use turned out to be that the earlier mark was used only in combination with a company name. In the composite sign H 15 Gufic, the element H 15 could be perceived as a mere product identifier rather than as an indication of origin independent of the company name Gufic. Perhaps if the earlier mark had been used on a stand-alone basis, or if it had been followed by the ® symbol, this might have supported a finding that the sign is recognised by the public as a trade mark.

As to likelihood of confusion, the Supreme Court confirmed that it could exist between the marks H 15 and Hecht H 15 if the earlier mark has an independent distinctive role in the composite sign, even if the goods in question are only similar. This finding appears to be in line with EU case-law, even though the CJEU's decision in *LIFE/THOMSON LIFE* concerned identical goods. However, finding a likelihood of confusion based on an independent distinctive role of the earlier mark should be approached with caution if the similarity of the goods and services is less than high.

Parallel Import Repackaging and Trade Mark Exhaustion: The Danish High Court Applies Merck Sharp & Dohme

Rachel Cockburn, Head of Global Brand IP, Ferring Pharmaceuticals

On 6 February 2026, the Danish Maritime and Commercial High Court (Sø- og Handelsretten) issued a judgment applying the Court of Justice of the European Union's ruling in Merck Sharp & Dohme (C-224/20). The decision provides important national court guidance on the circumstances in which parallel importers may lawfully repackage medicinal products into new outer cartons within the EU.

The judgment addresses a recurring tension between trade mark owners and parallel importers, and the delicate balance between the free movement of goods and the protection of intellectual property and patient safety: under what circumstances may a parallel importer replace the manufacturer's original outer packaging and product presentation? The Danish court's answer is clear and adopts a strict approach, confirming that new carton repackaging is permissible only where importers can demonstrate that the circumstances prevailing at the time of marketing in the importing country (rules on pack sizes, prescription practices etc.) impede the placing on the market of the product in the original packaging in which it was marketed in the exporting country.

Context

Parallel trade in medicinal products is a lawful consequence of the EU's internal market. Parallel importers purchase products in one EU Member State and resell them in another, benefiting from national price differences. To meet import market national regulatory or linguistic requirements, some adaptation of packaging may be necessary.

EU trade mark law provides that trade mark rights are exhausted upon first lawful placing of the goods on the EEA market but that exhaustion is not absolute. Trade mark owners may oppose further commercialisation where the condition of the goods is changed or impaired. In the pharmaceutical context, trade marks can be used to oppose repackaging unless the importer can demonstrate that repackaging is objectively necessary and otherwise complies with the so-called 'BMS Conditions' laid down by the European Court of Justice (Bristol Myers Squibb and Others, Joined Cases C 427/93, C 429/93 and C 436/93).

The scope of permissible repackaging has been refined through successive judgments. In Ferring Lægemedler (C-297/15), the CJEU emphasised once

again that repackaging must be objectively necessary for market access and may not be undertaken solely for commercial advantage.

Following the introduction of the Falsified Medicines Directive in 2019, some parallel importers argued that the new safety feature requirements made new carton repackaging unavoidable. An increase in new carton repackaging practices led to litigation in several Member States and referrals to the CJEU, including Merck Sharp & Dohme. The CJEU confirmed that the Directive did not change the established balance between the free movement of goods and trade mark law. A parallel importer is not entitled to repackage in new outer packaging unless it is objectively necessary to change the pack size before marketing the product in the importing Member State.

Sø- og Handelsretten's Ruling

The recent Danish High Court judgment represents the first higher court application of Merck Sharp & Dohme. It applies the ruling rigorously and provides practical clarification on several points of recurring dispute:

a. Falsified Medicines Directive obligations

The need to remove and replace anti-tampering devices or unique identifiers when repackaging does not, in itself, justify new carton repackaging. Compliance with pharmaceutical safety regulation must be achieved in a manner consistent with trade mark law.

b. National regulatory guidance

The court emphasised that guidance issued by national medicines agencies cannot modify or disapply EU trade mark principles. Member States may not authorise practices that undermine the rights of trade mark owners under EU law.

c. Information and supply chain transparency

Parallel importers must provide sufficient information to enable trade mark proprietors to assess the legality of proposed repackaging. Any concerns regarding misuse of such information fall outside trade mark law and may be addressed, where appropriate, under competition law.

d. Necessity and pack sizes

Perhaps most significantly, the court confirmed that EU law does not confer a right on parallel importers to market all pack sizes available in the importing Member State. Repackaging into a new outer carton is lawful only where the importer demonstrates that the pack size acquired in the export market cannot, in practice, be marketed in the import market. Evidence that a particular pack size enjoys higher demand or greater market share does not itself constitute objective necessity.

Comment & Conclusion

The ruling does not preclude all forms of repackaging. Both relabelling and new carton repackaging remain permissible where objectively necessary to market the product. The right of a parallel importer to repackage under certain conditions is, however, a narrow exception to the principle that a trade mark owner is entitled to oppose the marketing of products that have been changed by a third party. The burden of proof therefore rests firmly with the parallel importer.

For importers, the decision may affect operational flexibility and economics. New carton repackaging has been used to leverage price arbitrage between Member States and between product formats. Restricting this option may reduce the economic attractiveness of certain parallel trade activities.

For trade mark owners, the ruling supports a consistent approach to brand presentation and reduces the scope for alteration of the original packaging beyond what is strictly required. This affirms manufacturer brand owner abilities to preserve both product and trade mark integrity and presentation.

For practitioners, the decision offers valuable guidance on the evidentiary and legal standards applicable to repackaging of parallel imported medicinal products.

More broadly, the decision offers welcome clarity regarding the application of CJEU rulings and underscores the role of trade mark law in structuring the balanced relationship between competing imperatives in the EU pharmaceutical market.

The decision has been appealed by all defendants.

PTMG 107th Conference 23 – 24 March, 2026

Trade mark fest in the Bavarian home of innovation, Munich, Germany

Christina Tenbrock, HOYNG ROKH MONEGIER

Under the banner 'Trade mark fest in the Bavarian home of innovation,' PTMG's 107th conference took place in Munich from the 23rd to 24th of March 2026. And it was, indeed, a Fest!

For those arriving over the weekend before the conference, an optional dinner was held on Sunday at Königlicher Hirschgarten. This traditional Munich institution in Nymphenburg, serving food and drink since 1791, is said to be the world's largest beer garden. Bavaria is renowned worldwide for its deeply rooted traditions, distinctive customs, and warm hospitality - often captured in the motto of the world-famous football club FC Bayern: 'Mia san mia.' On that Sunday evening, the international guests experienced all of this first-hand. The menu brought together Bavarian delicacies in a 'light dinner': pork Leberkäse (which contains neither liver nor cheese), veal meatballs, pretzels and homemade potato salad, farm duck with roast potatoes and red cabbage, and, last but not least, Kaiserschmarrn with apple and plum ragout. The waiters and waitresses, naturally, were dressed in Lederhosen and Dirndl, and a traditional band provided the entertainment, even performing the customary Schuhplattler dance.

The conference itself kicked-off on Monday at the Hotel Bayerischer Hof, one of Munich's most legendary and historic hotels. Our charismatic Chairperson, Joanne Green of GSK opened the 107th conference by welcoming the international delegates, presenting the PTMG Committee and introducing the theme of the conference. With its carefully curated programme of highly relevant presentations and a truly international perspective, PTMG brought together dedicated professionals to address current issues of mutual interest, once again living up to its long-standing commitment to quality.

The first speaker was Young-Woo Yun, Head, Standards Section, WIPO, who presented WIPO's digital harmonization efforts. His presentation described a world in which fast-moving digital change, emerging technologies and fragmented administrative systems are forcing IP offices and users alike to rethink the way ownership data is created, verified and shared. WIPO's response, as he explained, is being developed through several forums and standards initiatives, including the



Joanne Green and Young-Woo Yun

Committee on WIPO Standards, the WIPO ICT Leadership Dialogue launched in 2025, and the AI Infrastructure Interchange launched in 2024. The practical goal is interoperability: lower costs, better productivity and a more reliable user experience across jurisdictions.

Particularly striking was Yun's description of WIPO's proposed Global IP Assignment Platform (GIPAP). GIPAP is designed to address a familiar frustration for rights holders: the need to record the same assignment separately in multiple jurisdictions, in different languages, and through different local requirements. The workflow shown in the presentation envisages a central portal through which users provide common and office-specific data, supported by local agents and office processing. Even at the MVP stage, the project signals a future in which the administrative burden around global portfolios may finally start to match the commercial reality of global pharmaceutical branding.

That future-facing discussion was followed by a much more immediate and tactical one. From Tresper IP, Thomas Tresper's presentation on litigating pharmaceutical trade marks in Germany distilled the procedural logic of a jurisdiction that remains highly attractive for trade mark enforcement while demanding careful forum and timing choices. Using a simple example of competing 'Blue' products, Thomas structured the litigation landscape around the pre-trial stage, preliminary injunction proceedings and the main



Thomas Tresper

action. He highlighted the practical importance of warning letters, cease-and-desist declarations, protective letters, counter-warnings and negative declaratory actions before the matter even reaches court. For practitioners, one of the clearest takeaways was the continuing importance of urgency in German preliminary injunction practice.

His comparison between preliminary injunctions and main actions was equally practical: injunctions offer provisional relief on credible evidence, but no damages and only where urgency exists; main actions require full proof, but permit broader claims, counterclaims and a final decision on the merits. In short, German pharma trade mark litigation remains powerful, but only for parties who understand its procedural tempo.

As an added bonus, the audience learned three German words; short, 'simple' to pronounce and easy to remember: Dringlichkeit, Verfügungsbeschluss and Schadenersatzfeststellungsanspruch!

In the ever-popular International Case Round-Up, Oliver Nilgen from Meissner Bolte shared some of the most interesting recent trade mark decisions from around the world. He selected cases on



Oliver Nilgen

absolute grounds for invalidity, relative grounds for invalidity, evidence of use and bad faith from the EU, followed by a selection of US, Canadian and Australian case law. Two particularly striking decisions concerned colour combinations presumed to lack inherent distinctiveness and the evidence required to establish acquired distinctiveness, both in relation to the relevant territory and the relevant public. Oliver also explained how the General Court, confirmed by the First Board of Appeal, found that the mark BIOREPAIR for goods intended for the care, treatment and hygiene of the teeth and the oral cavity, will be understood as 'biological repair' and must thus be considered descriptive. He then turned to a number of success stories, including SANYTOL, AGE PROTEOM, and OMNI POWER, before addressing relative grounds for

Conference Report: continued

invalidity and a series of further decisions. The factors relevant to assessing evidence on use were illustrated using a decision of the second board of appeal (R 768/2023-2) as an example and bad faith applications were illustrated using the JUVEDERM case as an example.

The presentation was enlivened by questions such as: 'What is the name of the famous fairytale-like castle in Bavaria?' and 'What is traditionally eaten during a 'Weisswurstfrühstück' in Bavaria?' allowing the audience to pick up some fun Bavarian trivia along the way. The presentation concluded with a glimpse into US case law introducing a case of trade dress infringement (Novartis AG v Novadoz Pharmaceuticals LLC) and another case of trade mark infringement and unfair competition (Gilead Sciences, Inc. v Meritain Health et al); a glimpse into Canadian case law, introducing a case between Samsung Bioepis Co., Ltd. and Novartis AG and a look at Australian case law, highlighting two opposition decisions.

Joanne then rounded up the afternoon by thanking the speakers and inviting delegates to the cocktail reception and the Gala Dinner at the Ballroom of the Bayerischer Hof. That evening, after thanking the many sponsors, Joanne invited Bruce Longbottom, a long-standing member of the PTMG Committee who retired in December to join her on stage for a presentation on behalf of the whole membership.



She thanked Bruce 'not just for the work done as a Committee member, but for the manner in which it was done, with warmth, generosity and professionalism'. A rousing round of applause from delegates wished Bruce on a well-earned retirement.

The Chair then advised delegates that the Autumn conference in Oman would be

postponed to 2027 and went on to make the much sought-after announcement regarding the Spring 2027 conference which will be held in Amsterdam. Later on, a glance around the stunning Ballroom suggested that everyone had thoroughly enjoyed the wonderful meal amid lively conversation with old and new friends, and that a few had lingered to continue their conversations at the story-filled bar of the Bayerischer Hof.



Soup kitchen at Antonius Kirche

Before opening Day two, our Chairman passed the floor to the Editor, who provided delegates with an update on the 'Giving Back to the Community' initiative which is now a regular feature at the Spring conference. Vanessa was happy to report that 8 delegates had joined her at a soup kitchen at Antonius Kirche in Munich and had assisted the charity Caritas in distributing lunch to the homeless. In the early afternoon, a second group of six



Soup kitchen at Korbinian Church

volunteers – PTMG alumni and guests led by Brand Action Ambassador Jackie Stelling – then went to another food distribution point near to the main train station. As one delegate said afterwards, 'I thought it was a great way to meet people in a more informal setting and I will definitely be keeping an eye out for it next year'.

Joanne thanked Vanessa for all her efforts in this connection and then introduced the first presentation of the day on 'Copyright and Specific Use Cases in Pharmaceutical Industry' by Lionel Schüpbach from Hoffmann La Roche. Speaking of a 'renaissance of copyright protection' and describing copyright as 'the superpower IP right', he guided the

audience through the threshold for copyright protection and highlighted the differences between Swiss and EU requirements.



Dr. Lionel Schüpbach

In her session on post-sale confusion, Laura Elliott of Stephenson Harwood defined post-sale confusion as confusion about trade origin that arises only after purchase, drawing on EU and UK decisions including Arsenal v Reed, Anheuser-Busch v Budvar, Picasso v OHIM and Daimler Chrysler,



Laura Elliott

Datacard v Eagle Technologies, Iconix v Dream Pairs and Thom Browne v Adidas, before placing the doctrine in a pharmaceutical context. Her examples were simple and persuasive: a patient only sees a prescription medicine after the pharmacist has dispensed it; a caregiver supplies a replacement medical device that the patient assumes is the trusted brand; a friend buys a cheaper OTC substitute that is then used as if it were the familiar product. In pharmaceuticals, the post-sale moment can therefore be the first meaningful consumer encounter. That perspective makes the doctrine unusually relevant for the sector. Laura's final matrix - jurisdiction, product, damage, public / consumer and regulators - suggested that the answer will vary across legal systems, but the underlying question is increasingly important: should trade mark law intervene where confusion emerges not at the point of purchase, but at the point of use, reliance or treatment? For pharma and medical devices, that is not merely a luxury-goods style concern about image; it can shade into trust, compliance and even safety.

A similarly strategic tone ran through the presentation by Marco van der Merwe and Duncan Maguire from Spoor & Fisher on African pharmaceutical markets. Their talk resisted the



Marco van der Merwe

Conference Report: continued

outdated idea of Africa as merely an import-dependent end market. Instead, through the case study of the dapivirine vaginal ring, they showed how Africa is increasingly becoming a site of innovation, clinical evidence generation and regulatory partnership. The ring's development, supported by a royalty-free non-exclusive licence, African-led clinical trials and collaboration with SAHPRA, WHO and EMA, was presented as proof that the continent can be a credible co-developer of high-impact health technologies, not just a recipient of finished products.



Duncan Maguire

At the same time, the speakers were refreshingly concrete about trade mark realities on the ground. Registration, they argued, is not optional but the safest course, given pirate filings, weak protection for unregistered rights, limited specialist courts and the evidentiary burden of passing off. Their overview of OAPI, ARIPO and Madrid designations across Africa underscored how dangerous it can be to assume that formal regional or international coverage equals enforceable protection. The slides on ARIPO's uneven effectiveness, the Tanzania Court of Appeal's ruling that ARIPO designations for mainland Tanzania are unenforceable, and the varying validity of Madrid designations in African jurisdictions all pointed in the same direction: Africa requires a country-by-country IP strategy, however tempting centralised systems may appear.



Florian Richter

Next up, from Hogan Lovells, Florian Richter's presentation on damages shifted the discussion from rights to remedies. His starting point was that trade mark harm is not limited to lost sales; it includes erosion

of brand equity, weakened exclusivity, dilution, trust loss and damaged associations. Yet his survey of German practice showed how difficult it remains to translate those realities into compensation. In Germany, claimants can pursue actual damage, licence analogy, infringer's profits, and at least in theory compensation for 'market confusion' but

in practice awards are rare, proceedings are lengthy, and plaintiffs face a major information gap because meaningful damage quantification requires data held by the infringer. The result, he suggested, is that settlements are often more rational than full damages litigation.

Richter's comparative overview of Italy, France and the UK reinforced that despite partial harmonisation under the Enforcement Directive, practical differences remain significant. France offers powerful tools such as the *saisie-contrefaçon*; Italy often deals with liability and damages in one judgment and makes heavy use of court-appointed experts; the UK preserves the alternative of damages or an account of profits, with disclosure obligations in the quantum phase and stronger cost recovery incentives. Across all systems, however, one theme recurred: hypothetical royalties are usually easier to prove than actual holistic brand damage. The talk was a useful reminder that for trade mark owners, winning on liability is only half the battle.



Mihai Rotaru

Representing EFPIA, Mihai Rotaru's presentation on international reference pricing, while not a classic trade mark topic, added an important commercial - policy perspective to the conference - by showing how pricing and access discussions are shaped by comparative clinical effectiveness, national negotiations, launch sequencing and cross-border price referencing. Rotaru's critique of IRP - especially its tendency to flatten price differences between higher- and lower-income markets, delay launches and undermine value-based pricing - served as a reminder that pharmaceutical brands operate within deeply interconnected market systems, not just legal silos.

Finally, the conference closed on the issue that perhaps most clearly linked trade mark protection to patient welfare. In 'Is your medicine safe?', Lucy Hambloch and Guillaume Ngo of Novartis described an anti-falsified medicines programme that combines intelligence gathering, prevention,



Lucy Hambloch

enforcement and stakeholder engagement. Their 2025 metrics were striking: 280 incidents, including 65 counterfeit cases, 160 diversion cases, 17 tampering cases and 38 theft cases; 49 enforcement cases; at least 2.9 million falsified medicine units seized; and 10,000 illegal online listings reported. The presentation mapped the full spectrum of falsified medicines, from fake products and tampering to theft and illegal diversion, and showed how forensic tools are now deployed in the field, including packaging verification, drug product authentication, lab investigations and severity assessments. This was not just a security presentation; it was a reminder that in pharmaceuticals, brand misuse can have immediate consequences for patient safety, and that anti-counterfeiting work is inseparable from public-health responsibility.

And with that, the conference came to a close. It was truly a conference packed with insightful and informative talks and engaging speakers. Sure enough, everyone is looking forward to the next Autumn gathering, the location of which is still to be confirmed!



Guillaume Ngo

New PTMG committee members



Jack Wessel

Gilead



Lisa Dellamura

MSD

E-Pharmacies in India: Making A Case For Regulation

Sonal Goel and Aarti Aggarwal, Remfry & Sagar

India's e-pharmacies operate within older statutes - the Drugs and Cosmetics Act, 1940 (DCA) and its Rules (DCR), which regulate manufacture, sale and labelling of drugs, and the Pharmacy Act, 1948, which addresses pharmacist qualifications. None are designed for digital transactions, leaving the sector in a grey zone.

Inventory-model platforms sell directly, while marketplace platforms act as intermediaries under the Information Technology Act, 2000 (IT Act). Some platforms also operate a hybrid model. Given the legislative and regulatory gaps, this evolving ecosystem, is increasingly inviting regulatory attention, pushback from traditional chemists, and judicial scrutiny.

The first concrete regulatory signal came in 2015, when the Drugs Controller General of India clarified that the DCR makes no distinction between offline and online sales and that compliance requirements apply equally to both. In 2016, FICCI introduced a voluntary Self-Regulation Code requiring medicines to be dispensed only through licensed pharmacies and mandating valid prescriptions for scheduled drugs. However, it lacked legal force.

A more detailed attempt followed in 2018 with the draft Sale of Drugs by E-Pharmacies Rules. These proposed definitions for e-pharmacies, a mandatory registration system, inspection mechanisms and procedures for online sale and distribution. They also prohibited online advertising of drugs, created monitoring and grievance-redressal systems, and barred e-pharmacies from dealing in narcotics, psychotropics, tranquilizers and Schedule X substances.

The draft Rules sparked litigation. Petitions before the Delhi and Madras High Courts sought blanket bans on e-pharmacies citing public-safety risks. In *Zaheer Ahmed v Union of India* (2018), the Delhi High Court prohibited online sale of medicines without a licence. Around the same time, the Madras High Court (*Tamil Nadu Chemists and Druggists Association v Union of India*) also imposed a temporary ban, but a Division Bench later set it aside, holding that enforcement lay with authorities under the DCA and DCR. The cases also highlighted model-specific defences: inventory platforms claimed valid retail licences, while marketplace platforms argued they merely connected consumers to licensed pharmacies.

In 2022, the draft Drugs, Medical Devices and Cosmetics Bill proposed a modernised framework but missed an opportunity to substantively address

e-pharmacies. It simply requires online sellers or distributors to obtain a licence and empowers the Government to frame rules for regulating online sale. At present, both the 2018 draft Rules and the 2022 Bill remain unnotified, keeping the legal status of e-pharmacies uncertain.

Judicial scrutiny

Indian courts, meanwhile, have repeatedly confronted the question: when does an online platform 'sell' a drug, and when is it only an intermediary? This distinction now sits at the core of enforcement actions involving e-pharmacies and online market-places.

Early concerns surfaced in 2017 in a case against Myra Medicines, where authorities and civil-society groups alleged that the platform enabled access to banned or prescription - only drugs without safeguards. These complaints highlighted fears around youth access, misuse of psychotropic substances and broader public-health risks.

Scrutiny escalated in 2023 when the Central Drugs Standard Control Organisation (CDSCO) issued show-cause notices to major platforms such as Amazon, Flipkart and Tata Img, accusing them of enabling the illegal online sale of prescription drugs. The platforms uniformly responded that they were intermediaries, not sellers, and that liability lay with the licensed pharmacies or third-party vendors using their services.

Courts have generally accepted this position where platforms demonstrate adequate diligence. The Karnataka High Court's 2021 decision in *Snapdeal Private Limited v State of Karnataka* is a key example. A third-party vendor had listed a prescription-only drug on Snapdeal, prompting prosecution under the DCA. The Court held that Snapdeal could not be treated as a seller because it did not manufacture, stock or supply the drug. Crucially, Snapdeal had clear contractual prohibitions on such listings, maintained a banned-products policy and removed the listing upon notice - satisfying the requirements for safe harbour under Section 79 of the IT Act. Proceedings were thus quashed.

The Delhi High Court's interim order in *IndiaMART Intermesh v The Central Drugs Standard Control Organisation & Ors.* (2025) adopts the same analytical framework. IndiaMART described itself as a 'digital directory' outside the scope of the DCA and despite repeated regulatory notices, the Court granted temporary protection, indicating that marketplace liability must be assessed through

intermediary-liability principles, not through traditional drug-sale concepts.

Together, these cases signal a judicial trend: liability for online drug listings depends on whether a platform controls inventory and maintains robust compliance, not on the mere presence of unlawful listings.

Addressing gaps

Alongside questions of platform liability, deeper structural issues require attention. Under the Pharmacy Act, 1948, only registered pharmacists may dispense medicines against a valid prescription, meaning e-pharmacies must ensure pharmacist oversight for every prescription order; a safeguard not always uniformly implemented. The Pharmacy Practice Regulations, 2015 also require pharmacists to counsel patients on dosage, usage and side effects, an interaction largely absent in online transactions.

Prescription authenticity is another challenge. Without a digital verification system, forged or duplicated prescriptions can be uploaded across multiple platforms, enabling over-purchasing and unsafe access. Although the DCR require pharmacists to mark prescriptions once dispensed, this safeguard is difficult to enforce online. Data-privacy concerns also persist, though India's new data-protection regime, notified in November 2025, is expected to strengthen standards for handling sensitive health information.

International models offer guidance. In the US, the National Association of Boards of Pharmacy's VIPPS (Verified Internet Pharmacy Practice Sites) accreditation system - supported by federal and state laws - ensures that online pharmacies meet strict standards for prescription authentication, safety compliance and third-party monitoring. The EU's Falsified Medicines Directive requires all legitimate online pharmacies to display a common EU logo linked to a national registry, enhancing consumer transparency and trust. In Japan, while certain OTC medicines may be sold online with real-time pharmacist involvement, for higher-risk products, prescription drug sales remain restricted. A 2025 legal revision will allow OTC pickup at convenience stores but with mandatory online pharmacist explanations.

Tapping into such models to shape its digital healthcare regime will enable India to promote innovation while protecting public health with clarity, consistency, and global best-practice alignment.

Pharmaceuticals v Cosmetics: EUIPO Report and practical implications for companies

Laura Pedemonte, Barzano & Zanardo

A report by the Boards of Appeal of the EUIPO (Similarity between pharmaceuticals and cosmetics, hereinafter referred to as the Report) explores the areas of overlap between pharmaceuticals and cosmetics, providing clear guidance on how to assess product similarity for trade mark protection purposes. This article offers a practical interpretation of the Report, with actionable insights to help inform strategic decisions in trade mark portfolio management.

A market in transition: why is it increasingly difficult to distinguish between pharmaceuticals and cosmetics?

The traditional boundaries between the pharmaceutical and cosmetic sectors are becoming increasingly blurred, due in large part to the growing convergence of distribution channels and marketing strategies. Moreover, evolving market trends have led to the emergence of 'hybrid' product categories – items believed to have curative or therapeutic (i.e. pharmaceutical) properties, despite being primarily aesthetic in nature.

Within this shifting landscape – which heightens the risk of brand confusion and legal disputes – the Report clarifies when two products falling under these broad categories may be considered similar for the purposes of assessing the likelihood of confusion between trade marks. The analysis provides concrete tools for stakeholders to ensure effective trade mark protection and to help prevent potential conflicts between similar signs in this space.

How do EU Laws define pharmaceuticals and cosmetics?

In drawing the line between pharmaceuticals (Class 5) and cosmetics (Class 3), the Report adopts definitions from European legislation:

- Pharmaceutical products, as defined in Directive 2001/83/EC, Article 1(2), are substances or combinations of substances intended to treat, prevent, or diagnose diseases, or to modify physiological functions through pharmacological, immunological, or metabolic action.
- Cosmetic products, as per Regulation (EC) No. 1223/2009, Article 2(1)(a), are substances or mixtures intended for external use on the human body (e.g. skin, hair, nails) or on the teeth and oral mucosa, for the sole or primary purpose of cleaning, perfuming, altering appearance, protecting, maintaining condition, or correcting body odors. Notably, products intended to be ingested, inhaled, injected, or implanted are explicitly excluded from

the definition of cosmetics (Article 2(2)). While these definitions appear clear, they leave room for interpretation – particularly when it comes to multifunctional products such as cosmeceuticals (cosmetics with bioactive ingredients), which are often at the centre of trade mark disputes.

When can pharmaceuticals and cosmetics be considered similar?

Through a systematic analysis of European case law, the Report outlines the main criteria for assessing the similarity between pharmaceuticals (Class 5) and cosmetics (Class 3). Below is a summary of the key findings:

1. Pharmaceuticals v Cosmetics (excluding perfumes and essential oils) – General Categories

The case law reflects a general consensus in recognizing a certain degree of similarity between the broad categories of pharmaceuticals and cosmetics (with the exception of perfumes and essential oils). The Court of Justice typically identifies a low degree of similarity, while the Boards of Appeal assess similarity as ranging from low to medium. This assessment is based on factors such as shared purpose (e.g. skin or hair care), similar distribution channels (pharmacies, specialized stores), overlapping target consumers (general public), comparable form (gel, cream), similar modes of application (external use) and, in some cases, the same commercial origin (e.g. products sold under the same brand). Where common commercial origin is demonstrated, a medium degree of similarity may be justified.

2. Topical pharmaceuticals v Cosmetics (excluding perfumes and essential oils)

Topically applied pharmaceuticals and certain cosmetics often share form, function, method of use, sales channels and ingredients. As a result, case law typically assigns a medium level of similarity in these cases.

3. Pharmaceuticals with systemic therapeutic effects (non-topical) v Cosmetics

Pharmaceuticals intended for internal use or systemic effects are generally dissimilar from cosmetics. These products differ in purpose, method of use, distribution channels and target consumers, and they are not considered complementary.

4. Pharmaceuticals v Perfumery Products

Medicines and perfumery items (including deodorants and essential oils) are generally

dissimilar, as they serve different functions, are sold through different channels and cater to different audiences.

Only in rare cases – such as certain deodorants or essential oils – has a low degree of similarity been recognized, and even then, only as part of broader contextual evaluations.

Conclusions and practical recommendations for trade mark owners

While the legal distinction between pharmaceuticals and cosmetics is well established, real-world practices often blur the lines – especially with the rise of hybrid products like cosmeceuticals. This overlap can have a direct impact on trade mark protection, particularly when it comes to evaluating product similarity and the likelihood of consumer confusion. In this increasingly dynamic and competitive landscape, companies should consider adopting targeted strategies to manage and protect their brand portfolios effectively. In particular:

- **Choose distinctive brands:** Selecting more distinctive, less descriptive trade marks can reduce the risk of confusion, especially in markets saturated with similar or hybrid products.
- **Conduct comprehensive clearance searches:** Carry out prior rights searches covering both Class 3 (cosmetics) and Class 5 (pharmaceuticals) to identify potential conflicts, even where the product categories seem unrelated.
- **Strategic trade mark registration:** Consider registering in both Classes 3 and 5 to ensure broader protection, especially for multifunctional products (e.g. a cosmetic with secondary therapeutic benefits or a topically applied pharmaceutical).
- **Monitor the market and registries:** Ongoing surveillance of the market and trade mark filings in both classes is essential for detecting and addressing potential infringements early.
- **Regularly reassess your IP portfolio:** As the market evolves and new hybrid products emerge, periodically review your trade mark portfolio to ensure it covers all relevant product lines adequately. Finally, these considerations should be embedded within a company's broader strategic planning – especially when developing new products. Setting up intellectual property protections early in the product development cycle not only reduces legal risk but can also serve as a significant competitive advantage in a crowded and tightly regulated market.

Mission Impossible? A Refresher on Clinical Trials and Proper Reasons for Non-Use of Pharma EUTMs

Celia Tao, Pinsent Masons

The development of a pharmaceutical product often spans many years. Mandatory clinical trials and the need to obtain marketing authorisation frequently delay commercial launch and this creates tension with trade mark law. Under EU law, an EU trade mark may be revoked if it is not put to genuine use within five years of registration.

EU law allows proprietors to rely on a 'proper reason for non-use' to resist revocations. Regulatory delays such as clinical trials are often referenced by the EUIPO as a potential justification. In practice, however, case law shows that this is a difficult argument to run

The Touchstone Case: Viridis Pharmaceutical Ltd v EUIPO

Since 2019, the CJEU's decision in *Viridis Pharmaceutical Ltd v EUIPO*¹ has become the leading authority on whether regulatory delay, such as time spent in clinical trials, can justify non-use of a pharmaceutical trade mark. *Viridis*, a German pharmaceutical company, applied in 2003 to register the word mark *BOSWELAN* in Class 5, obtaining the registration in 2007. In 2013, the registration was revoked for non-use at the request of Hecht-Pharma. At that time, *BOSWELAN* had not obtained marketing authorisation and had been used only in the context of clinical trials.

The case ultimately reached the CJEU. While the CJEU did not rule out in principle that clinical trials might justify non-use, it reiterated the prevailing law that any obstacle as a proper reason of non-use must be 'independent of the proprietor's will' and have a 'direct relationship with the mark'. On the facts, the Court found that the premature filing of the mark, the timing and the funding of the clinical trials were all within *Viridis*'s control. Accordingly, the resulting delay stemmed from its own development decisions.

Viridis therefore illustrates that proper reasons for non-use based on clinical trials are scrutinised closely and why they are difficult to rely on in practice.

Recent Practice in Action: IMUNO BCG

In a recent revocation decision² before the EUIPO concerning the mark *IMUNO BCG*, the difficulties of relying on clinical trials as a proper reason for non-use were again brought to light. *IMUNO BCG* is a

vaccine used in the treatment of superficial bladder cancer. Unlike *Viridis*, the underlying product is a fully developed one which was launched in Brazil in 2006. In 2017, the trade mark proprietor, Fundação Ataulpho de Paiva (FAP), entered into a technology transfer agreement with a Spanish company with a view to launching the product in Spain. According to FAP, the Spanish Medicines Agency required local clinical studies. The study should have been completed in 2023 but compliance with governmental requirements and the Covid-19 pandemic delayed progress. On this basis, FAP relied on a proper reason for non-use to defend the revocation action.

While the EUIPO agreed with FAP's position in principle, it criticised the evidence submitted. The only document relating to the clinical studies was a study summary, which the EUIPO considered to be an internal document with limited probative value. It noted that further evidence, such as correspondence with the Spanish Medicines Agency, could and should have been provided.

How can a Trade Mark Owner Improve their Position?

What emerges most clearly from *Viridis* and *IMUNO BCG* is not a rejection of clinical trials as a justification for non-use, but the difficulty of proving that the non-use genuinely results from circumstances independent of the proprietor's will. When faced with a revocation action, how can a trade mark owner successfully defend its position where marketing authorisation has not yet been granted?

1. Easier if the marketing authorisation application is filed

First, the stage reached in the regulatory process is crucial. An owner is more likely to succeed where an application for marketing authorisation has already been filed, as responsibility for regulatory delay can then be said to have shifted to the regulator.

This was illustrated in a case³ cited by FAP in *IMUNO BCG*, where the trade mark owner, Ferring B.V., successfully resisted revocation by relying on a filed marketing authorisation application, even though it had been submitted relatively late. At the time the revocation action was brought, Ferring had already filed its EU marketing authorisation application. The key issue was that Ferring had chosen to prioritise finalising of the US marketing

authorisation before initiating the EU process. The revocation applicant argued that Ferring had delayed filing in the EU until just 19 days before the EUTM became vulnerable, despite knowing that the process would take at least a year.

The EUIPO accepted that Ferring was entitled to adopt that strategy and held that it would be unreasonable to impose additional requirements as to the precise timing of the EU filing. Since the EU marketing authorisation proceedings impeded use during the relevant period, they constituted a proper reason for non-use.

2. Keep the records, even the pre-authorisation ones

Secondly, as *IMUNO BCG* demonstrates, it is essential to retain a complete evidential record of the regulatory pathway relied upon. An earlier case, *AmBil*⁴, clearly illustrates this point. There, the proprietor successfully defended its registration not only by showing that a marketing authorisation application had been filed, but also by producing pre-authorisation correspondence, including letters from the MHRA relating to regulatory meetings and guidance on clinical, non-clinical and quality requirements. Although the cancellation applicant argued that such correspondence could not establish administrative obstacles as they pre-dated the application of the marketing authorisation, the EUIPO held that it showed the work on the procedure had started early on and that the proprietor had not remained inactive but had maintained ongoing contact with the competent authority.

¹ *Viridis Pharmaceutical Ltd v EUIPO*, Case C 668/17 P, EU:C:2019:557

² EUIPO Cancellation Division, Decision of 26 August 2025, Cancellation No 68 204 C (Revocation), *Medac Gesellschaft für klinische Spezialpräparate m.b.H. v Fundação Ataulpho de Paiva*, EU trade mark No 13 856 935 (*IMUNO BCG*)

³ EUIPO Cancellation Division, Decision of 24 February 2020, Cancellation No 12 497 C (Revocation), *Allergan, Inc. v Ferring B.V.*, EU trade mark No 8 679 441 (*NOCDURNA*)

⁴ EUIPO Cancellation Division, Decision of 30 January 2017, Cancellation No 9 733 C (Revocation), *Gilead Sciences Europe Ltd v Taiwan Liposome Co., Ltd*, EU trade mark No 7 034 23 (*AmBil*)

Long-running Merck dispute culminates in GBP £5.67m damages award

Ben Buray and Gill Dennis, Pinsent Masons LLP, London

The long-running trade mark litigation between German-headquartered Merck KGaA (Merck) and US-headquartered Merck Sharp & Dohme LLC (MSD) recently concluded with a High Court judgment assessing the damages payable by MSD for its infringement of Merck's trade mark rights in the UK. Damages inquiries for trade mark infringement by the English courts are rare. In this judgment, the court considered whether trade mark damages can be treated in the same way as other intellectual property rights and what appropriate valuation methods could be utilised to assess the quantum for those trade mark infringements.

Background

The dispute centred on coexistence arrangements between two major global pharmaceutical companies, Merck and MSD. Merck has exclusive rights to use the MERCK mark globally, except in North America. MSD only has exclusive rights to use the MERCK mark in North America and uses the name MSD in other markets. Formal coexistence arrangements were established between Merck and MSD in 1955 and later renewed in 1970. There is a long and complex procedural history. Despite proceedings having been commenced in 2013, the High Court judgment finding that MSD had infringed Merck's United Kingdom trade mark rights and breached the 1970 coexistence agreement was not delivered until 2020. MSD was held to have carried out various acts amounting to direct use of MERCK in the UK. This included US-branded merck.com webpages being accessible in the UK, webpages using MERCK rather than MSD name and logo, UK consumers being directed to contact MSD personnel with @merck.com email addresses and MSD staff corresponding with UK consumers by reference to 'Merck products'. There were also further acts which breached the 1970 coexistence agreement.

Key issues for the court

The court's damages inquiry focused on three key questions:

- Whether 'licence fee damages' were appropriate for trade mark cases;
- If so, whether there was a basis for Merck to rely on a 'comparables analysis' to value the damages that should be payable by MSD; and
- Alternatively, whether the damages assessment should be based on the 'economic benefits' obtained by MSD in using the trade mark.

Licence fee damages assessment

Licence fee damages (also known as 'negotiating damages') is a well-established approach to damages assessment for intellectual property infringements where there is no normal rate of profit or established licence royalty. However, it has been rarely considered in trade mark infringement cases. Most damages inquiries have been in patent or copyright infringement cases.

The assessment has the 'user principle' at its core: a hypothetical negotiation between a willing licensor and licensee to determine a notional licence fee for the level of damages. MSD contended that licence fee damages were inappropriate in the circumstances because Merck would never have realistically licensed its umbrella MERCK brand to a direct competitor. MSD also argued that, while the user principle was appropriate for patent infringement (essentially paying for the use of the invention), the same could not be said for trade mark cases, particularly where the mark concerned was not a mark 'available for hire'.

The Court rejected MSD's arguments and confirmed that trade marks are 'quintessential commercial property rights, for which a licence presents no inherent difficulty'. No distinction should be made around the availability of negotiating damages between the different intellectual property rights.

A comparables analysis

In a comparables analysis, valuation experts typically utilise comparable royalty rates in similar licences in the relevant market. In Merck's best-case scenario, it claimed damages of GDP £50.5 million. This was calculated using a 0.33% royalty rate from a 'comparable' intragroup brand licence as there were otherwise no direct comparables in the pharmaceuticals industry for umbrella corporate brand licences. The court was unwilling to accept brand licences in other sectors (including licences of consumer brands VIRGIN and easyGroup) as adequately comparable. The court was also unwilling to accept the intragroup brand licence as a reliable comparator, finding that there was insufficient reliability in the data underpinning the royalty rate of 0.33% to provide any 'meaningful assessment' for damages.

As Merck was not able to identify any reliable comparables for the licence fee

damages assessment, the court had to consider the alternative 'economic benefits' approach.

The 'economic benefits' approach

The 'economic benefits' approach measures the infringing party's quantifiable benefits (the 'ceiling price') and balances that against the incremental loss of the rights holder from the notional licence (the 'floor price'). The assessment then considers the commercial context and bargaining position of the parties to identify the appropriate 'notional licence fee' between the ceiling price and the floor price. There was consensus between Merck and MSD that the notional licence fee should be set at the ceiling price. It was therefore only necessary for the court to consider which benefits obtained by MSD were quantifiable for damages purposes. The court held that these included:

- Avoided website costs of approximately GDP £4.33 million: the benefit obtained by MSD from not having implemented geo-blocking measures for its North American web site or maintained mirrored MSD-branded pages of their website for the global market;
- Avoided social media costs of approximately GDP £780,000 on a similar basis as the avoided website costs; and
- Avoided marketing costs of approximately GDP £566,000. Despite this being an 'uncertain' exercise, evidence from Merck of a 2013 rebranding project provided a proxy to value MSD's avoided marketing costs.

Other potential benefits were discounted, such as avoided email migration costs, as those would be incurred by MSD in any event once the notional licence had expired.

On the economic benefits analysis, Merck was awarded GDP £5.67 million in damages prior to adjustments for inflation and discounting measures.

Significance of the decision

This case provides helpful clarification that a 'licence fee damages' assessment is appropriate for trade mark infringement cases, including in the pharmaceutical sector. However, brand owners should be ready and willing to adopt an economic benefits analysis when exploring brand value unless reliable licence fee comparables exist.

International Update

KAZAKHSTAN

CWB

On 24 November 2025, Kazakhstan's President signed Law No. 233-VIII, effective 25 January 2026, which amends several key IP acts, including the Civil Code, the Law on Trade Marks, Service Marks, Geographical Indications and Appellations of Origin of 26 July 1999, the Patent Law of 16 July 1999 and the Law on Copyright and Related Rights of 10 June 1996.

The key changes introduced by the new law include the following:

- Accelerated preliminary examination option: Must be completed within 10 working days from the trade mark application filing date, whereas the standard preliminary examination typically takes about one month.
- Accelerated substantive examination option: Must be completed within three months from the filing date, whereas the standard substantive examination typically lasts about seven months under the current version of the Trade Mark Law and its implementing regulations.
- Extended opposition period: Under the amended Art. 11-2(1) of the Trade Mark Law, the opposition period for published trade mark applications has been extended from one month to two months. This provides brand owners and their representatives more time for monitoring, reviewing, and preparing legal arguments to protect their rights.
- Suspension of the examination upon filing a lawsuit: Under Art. 13(7) of the Trade Mark Law, suspension of trade mark application examination is now permitted not only when an opposition has been filed with the Kazakh Board of Appeals, but also when a lawsuit has been initiated in court. This amendment aligns administrative and judicial processes and prevents conflicting decisions during the ongoing litigation.
- Postponement of Board of Appeals hearings: Amendments to Art. 41-2(4)(2) of the Trade Mark Law broaden the right to request adjournment of opposition hearings. Previously limited to the opponent, this right has now been extended to any party to the dispute, including the trade mark applicant.
- Updated definition of protected rights under the Civil Code: Amendments to Art. 972(1) introduce modern terminology and expand the list of protectable IP rights. The new wording includes "works of decorative and applied art" and "computer programs (software)". Similar amendments to Art. 7(1) of the Copyright Law modernise the definition of copyrightable works to accommodate broader protection for contemporary creative works.

Kazakhstan's new IP legislation modernises the system by expanding protection for contemporary creative works and by streamlining IP procedures. It creates both

opportunities and obligations—trade mark owners must adapt to new timelines, while authors, software developers, and designers may benefit from clearer recognition of their rights.

LIBYA

CWB

Libya's Trade Mark Office has announced a significant change in trade mark renewal procedures. Effective immediately, all trade mark renewals will be accepted for a fixed period of ten (10) years only, and the option of annual renewals is no longer available.

This change aligns with the country's Trade Mark Law, particularly Article 1257, which stipulates that trade mark protection periods are set at ten years, renewable for an identical period.

Furthermore, trade mark owners who previously renewed their marks under the former short term option will now need to submit additional renewal applications along with the accompanying official fees to cover the remaining years of the full ten-year period.

For trade marks that have not yet been renewed for the full period, the official renewal fee per single trade mark registration, per class, will be approximately USD \$20,000 for a ten-year protection period. Libya's Trade Mark Office has introduced a series of measures that have significantly affected trade mark practice in the country. These include amendments to official fees, a substantial increase in renewal fees for the full term of protection, and the suspension of one year or multi year renewals in favour of mandatory renewals covering the full ten year term.

In addition, re-filing of trade marks has been suspended until the final cancellation decision is issued and published in the Official Gazette. It is also reported that the Trade Mark Office has become affiliated with the Commercial Registry Authority.

In January 2026, further changes were issued concerning the registration and renewal of trade mark agent licences in Libya. Under the new requirements, the agents must:

- Ensure that their commercial registration explicitly includes the activity of registering foreign trade marks
 - Submit a professional liability insurance policy
 - Hold an ISO 9001:2015 quality certification
- Agents were granted a period of ten days to comply.

MALDIVES

Denise Mirandah and Surabhi Pathak, mirandah asia

A new Trademark Bill establishing the Maldives Trademark Law (Law No 19/2025) and the Maldives Intellectual Property Office (MIPO) was ratified in November 2025 by President Dr Mohamed Muizzu, creating a statutory basis for trade mark protection in the country, inter alia, with a view to further economic development of the nation.

MIPO was established on 1 January 2026 and the new Trademark Act will come into force twelve months after publication i.e., on 11 November 2026.

This development marks a meaningful advancement for the trade mark landscape in Maldives by introducing a formal legal framework for the registration and management of trade marks, including trade mark infringement guidelines and measures. It is a welcome step from the earlier practice where trade marks could only be protected by way of publishing cautionary notices, which was merely publication in the local newspapers informing the public of one's ownership rights in its trade mark(s).

Some of the prominent aspects of the new law are as follows:

- Certification marks and collective trade marks are allowed
- In addition to the usual six-month priority claims based on foreign filings, the new Act also allows for exhibition priority for marks showcased at certain recognized exhibitions
- There is a two-step examination process including a formality examination followed by a substantive one.
- There are enhanced enforcement measures against trade mark infringement and counterfeits including civil and criminal actions; penalties and customs border protection.

Trade mark owners who had previously published cautionary notices are now required to file an application for their trade marks within 12 months from the effective date of the Act i.e. until 11 November 2027. Therefore, trade mark owners should start reviewing their existing trade mark portfolios in Maldives and collate all documents such as their cautionary notices and any use in exhibitions to be ready for the transitional period and file their trade mark applications under the new law post-11 November 2026.

Till the IP Office is completely set up, which is anticipated around end of this year, trade mark owners may continue to publish cautionary notices

SINGAPORE

Denise Mirandah and Ellis Kusumo, mirandah

In *Cosmetic Warriors Limited v Genpulse Pte Ltd* [2026] SGIPOS 1, the Intellectual Property Office of Singapore (IPOS) dismissed an opposition against the registration of a composite mark, in Class 44.

Background

The Applicant, Genpulse Pte Ltd, is a Singapore company in the business of delivering AI-driven dermatological and trichological solutions. The Opponent, Cosmetic Warriors Limited, is part of the LUSH Group, a global skincare and cosmetics business, and the proprietor of the LUSH trade marks registered in Singapore.



LUSHAIR

Continued on next page

International Update continued

On 22 January 2024, the Applicant sought to register a composite mark in Class 44 for beauty and skin care services, consisting of a stylized letter 'L' device, taking the shape of a strand of hair encircled in an orb, and the word LUSHAIR. The Opponent opposed the application mark under Sections 8(2)(b) (similarity), 8(4) (well-known marks), and 8(7)(a) (passing off) of the Trade Marks Act. The Principal Assistant Registrar dismissed the opposition on all grounds.

Technical Distinctiveness and the Threshold of Marks Similarity

The Registrar applied the established 'step-by-step' approach, which requires an assessment of (1) marks similarity, (2) goods or services similarity, and (3) likelihood of confusion. If either marks' similarity or goods or services similarity is not established, the inquiry ends without the need to consider likelihood of confusion.

A critical aspect of the decision was how different forms of distinctiveness operate within this framework.

First, inherent technical distinctiveness is assessed at the marks-similarity stage (Stage 1). It calibrates the height of the similarity threshold: a mark with high inherent distinctiveness enjoys a correspondingly high threshold before a competing sign will be considered dissimilar. In this case, the Registrar found that the LUSH trade marks possessed an average, medium level of inherent technical distinctiveness. As a result, there is no 'high threshold' to be crossed before the application mark is considered distinguishable from it.

Second, acquired technical distinctiveness does not feature at the marks-similarity stage; it should instead be considered, where relevant, at the likelihood of confusion stage (Stage 3). This ensures that the initial comparison of marks focuses on their inherent qualities rather than their market reputation, preserving conceptual clarity in the analysis.

Permissible and Impermissible Factors in the Confusion Inquiry

On the likelihood of confusion, the Registrar distinguished between extraneous factors based on whether they are inherent to the goods/services.

Permissible factors are those inherent in the goods or services themselves, such as their nature, price, and the degree of care or fastidiousness exercised by consumers. In relation to Class 44 beauty and skin

care services, the Registrar observed that consumers are typically 'highly mindful' and exercise a significant degree of care, which reduces the likelihood of confusion.

Impermissible factors are those differences created by a trader's differentiating steps which are not inherent in the goods or services. These include 'superficial marketing choices' that a trader might change from time to time. The Registrar explicitly categorised the Opponent's reliance on mobile applications, AI technology, and brand collaborations (specifically mentioning partnerships with 'Mario', 'Barbie', and others) as examples of such impermissible factors. The Registrar concluded that because these features are incidental and related to marketing rather than being inherent to the goods (skin/hair care) or services (beauty/skin care), they 'should therefore not be factors in assessing the likelihood of confusion'.

Outcome

The Registrar concluded that the Applicant's mark was visually, aurally, and conceptually dissimilar to the LUSH trade marks.

- Visual: The composite mark was dominated by the stylized 'L' device and a longer seven-letter word.
- Aural: The strong '-HAIR' or '-AIR' ending balanced the LUSH sound, creating a dissimilar sound.
- Conceptual: While LUSH evokes notions of attractiveness, luxury, and vigorous, healthy growth, LUSHAIR evokes the specific idea of 'hair that is full, healthy and luxuriant'.

As the similarity threshold was not met, the ground under Section 8(2)(b) failed at the first step. This lack of similarity also meant the Section 8(4) ground could not be established, and the essential element of misrepresentation required for passing off under Section 8(7)(a) was likewise not made out.

SOUTH AFRICA

Tammi Pretorius, ENS Africa Background

The South African Health Products Regulatory Authority (SAHPRA) has recently updated its Guideline for proprietary names for medicines governing the proprietary names of medicines and setting out the criteria by which proposed medicine names are evaluated for registration in South Africa.

SAHPRA is the entity that is responsible for the regulation (monitoring, evaluating, investigating, inspecting and registering) of medicines and health products to ensure their safety, efficacy and quality. Its Names and Scheduling Unit evaluates the suitability and applicability of any proprietary name proposed to be used in connection with a medicine. The recently revised naming guideline provides direction to applicants, holders of certificates of registration, and regulatory pharmacists on how SAHPRA assesses the suitability of proposed medicine names.

The guideline addresses three broad types of names:

1. Product Names are the proprietary names of individual, unique, registered medicines and their line extensions. All SAHPRA approved proprietary names must be unique and distinctive, readily recognisable, and differentiable from every other proprietary name to avoid look-alike and sound-alike confusion.
2. Umbrella Names are collective proprietary names used for a range of co-branded but differentiated products targeting specified conditions or therapeutic goals. SAHPRA expresses concerns that umbrella names may blur product differentiation for consumers, potentially impacting appropriate product selection.
3. Company Identifiers or House Brands permit manufacturers to associate their company name with their products, facilitating brand recognition among patients and healthcare professionals.

In terms of the guideline, any proposed name is tested against the possibility that it may directly or indirectly pose public health or safety concerns, be misleading, or place patients and consumers at risk.

The guideline includes that proprietary names should preferably comprise a single invented word, and applicants are encouraged to propose names that are as short as practicable. According to SAHPRA, multiple-word names increase the risk of confusion and abbreviation by users. Hyphenated words and certain symbols (+, &, #, @, =, [,], ') are prohibited while terms implying absolute efficacy (such as MAX, CURE, or STOP) are discouraged. Ordinary English dictionary words and popular personal names (whether living, dead, or fictional) will not usually be accepted as proprietary names. The use of qualifiers or abbreviations as part of a product name is acceptable where they provide additional

[Continued on next page](#)

International Update continued

product information, such as strength, route of administration, or dosage form.

As set out in the guideline, approval of a proprietary name by SAHPRA offers a form of exclusivity over the use of that name in a manner both analogous to, and distinct from, the form of exclusivity acquired by the registration of a medicine name as a trade mark in terms of the South Africa's Trade Marks Act (No. 194 of 1993). Both registration systems operate independently and serve different purposes, with SAHPRA's name approval rooted in patient safety and public health, whereas trade mark registration is rooted in the protection of intellectual property and commercial interests.

Critically, registration of a trade mark for a medicine name under the Trade Marks Act will not be taken into consideration when SAHPRA assesses the acceptability of a proposed proprietary name for a medicine. This means that a pharmaceutical company cannot rely on an existing trade mark registration to secure SAHPRA's approval for use of that name on a medicine. SAHPRA applies its own criteria, centred on safety and clarity, with its assessment evaluating whether a name could be confused with another medicine's name in print, handwriting, or speech and taking into account numerous factors including registered indications, intended patient populations, dosage forms, routes of administration, strengths, dispensing settings, scheduling status, and the potential for harm from prescribing, dispensing, or administration errors.

Additionally, proprietary names must not be misleading with respect to therapeutic effects, product composition, or safety. SAHPRA subscribes to the World Health Organization's guidelines protecting International Non-Proprietary Names through the use of INN stems.

The guideline also expressly disclaims any role in determining whether a particular proprietary name may infringe another's intellectual property rights. It states that this issue 'cannot be one of SAHPRA's concerns and is therefore not taken into account during consideration of the acceptability of a proposed proprietary name.'

Similarly, SAHPRA's approval of a proprietary name cannot be relied upon to support any claims in respect of intellectual property rights over that name. This means that securing SAHPRA approval does not establish or confirm trade mark ownership or validity.

So what does all of this mean for when it comes to naming new health products in South Africa?

Choosing medicine names must be carefully and strategically considered, as

part of a two-pronged clearance approach, balancing 'safety-distinctive' with 'marketing-distinctive' name options. A name that is a strong trade mark candidate (highly distinctive) can still be rejected by SAHPRA on safety or misleading grounds. Conversely, a name approved by SAHPRA can still be unavailable or risky from a trade mark perspective because SAHPRA does not test or consider infringement.

Ultimately, the 'best' name will be one that is both distinctive, protectable and enforceable as a trade mark, and regulatorily safe with low look-alike/sound-alike risk. Although the guideline confirms that SAHPRA will take into account where a name has been approved by another major regulatory authority, foreign approval does not automatically guarantee acceptance by SAHPRA and so what is acceptable in one jurisdiction might not be acceptable in South Africa specifically. Developing multiple name options as ranked alternatives within a portfolio of options (noting that SAHPRA recommends submitting three proposed proprietary names per application) and simultaneously conducting trade mark clearance searches on those multiple options is recommended.

This 'timing trap' arising from SAHPRA's naming requirements and approval process, and third-party IP rights will also likely require applicants to integrate regulatory naming review and trade mark clearance as a single project plan with shared decision points going forward, rather than handing off sequentially between regulatory and trade mark teams.

It will be interesting to see what practical effect the guideline will ultimately have on the proprietary name approval process in South Africa.

YEMEN - ADEN

Jehad E Hasan and Fettah Mohcine, JAH Intellectual Property

The Trademark Office (TMO) in Yemen-Aden has recently implemented a rigorous and mandatory procedural shift that directly impacts the global pharmaceutical and medical supplies sector. This change marks a departure from standard regional practices, introducing a unique layer of bureaucracy for any trademark applications falling under Class 5. For several months, the TMO has been moving toward a more structured oversight of healthcare-related marks, and this latest development represents the finalization of that strict regulatory stance.

Under the new directive, Class 5 applications will no longer be processed through the traditional registration track. Instead, all applicants are now required to

submit a formal declaration explicitly stating that the trade mark is being registered solely for 'protection purposes' and will not be used commercially within the Yemeni market. This declaration is not a document drafted by the applicant or their legal counsel; rather, it is a standardized legal instrument prepared internally by the legal department of the Ministry of Industry and Trade in Aden.

This procedural requirement carries specific administrative and financial obligations that brand owners must factor into their intellectual property budgets. Each mandatory declaration is subject to an additional official payment fee of YR 30,000, which is approximately USD \$30. While the fee itself is relatively modest, the logistical necessity of coordinating with the Ministry's legal department to obtain the prepared text adds a significant step to the filing timeline.

It is vital to recognize that this declaration serves exclusively as a procedural prerequisite for achieving trade mark registration for protection purposes. It is essentially a 'holding' status that allows a brand to be recorded on the register, thereby preventing third-party infringements or bad-faith filings, without necessitating immediate market entry. However, it is important to emphasize that this registration does not grant the right to distribute or commercialize products within the territory.

While the TMO and the Ministry of Industry and Trade oversee the 'protection-only' registration, the actual use, importation, and distribution of Class 5 goods remain strictly subject to the Supreme Authority for Medicines and Medical Supplies. To move beyond mere protection and into actual market participation, brand owners must obtain a specific, separate license from this Supreme Authority.

The TMO has now signaled that the 'exception era' is over. The office is strictly enforcing these procedures for all new trade mark applications in class 5. No application in this category can proceed to the next stage of registration until the Ministry's declaration is filed and the associated fees are settled. This shift is likely a response to the need for greater transparency and control over the pharmaceutical supply chain in the region.

Strategic Recommendations for Brand Owners

For pharmaceutical companies with interests in the MENA region, the Yemen-Aden development necessitates an immediate audit of their class 5 portfolios. If a brand is relying on a pending application or planning a new filing, it must be prepared for the mandatory 'protection-only' declaration.

Trade mark Protection in the Pharmaceutical Sector and the Fight Against Illicit Markets: Legal Trends and Strategic Insights from Italy

Laura Pedemonte, Barzano & Zanardo

The Pharmaceutical Industry remains one of the most active sectors in trade mark registration, driven by continuous product development and intense market competition. In this context, trade marks serve a dual function: they differentiate products commercially while supporting safe prescribing practices and preventing clinical errors. Because confusion between medicinal products may entail serious health risks, brand protection in this field carries regulatory, legal, and public-health implications that go beyond traditional trade mark strategy.

Weak Marks and the Risk of Market Interference

Pharmaceutical trade marks often rely on evocative structures that reference active ingredients, therapeutic indications, or physiological targets. The widespread use of prefixes, suffixes, and medically oriented linguistic elements facilitates regulatory approval and enhances recognition by healthcare professionals. However, these 'weak marks' inherently possess limited distinctiveness, increasing the probability of overlapping semantic or phonetic elements across different products. As such, disputes in this sector frequently revolve around small variations that may or may not suffice to avoid confusion for an attentive and specialized public.

Italian Court Practice

Although the likelihood-of-confusion test leaves room for judicial discretion, recent Italian case law reflects a tendency to set boundaries on the coexistence of weak marks, thereby ensuring concrete protection where the risk of confusion is significant. Courts have deemed several pairs of signs confusingly similar, including VENOLEN and VENOVEN, LIPONORM and LIPONAM, MYCOSAN and MICOSAN, and REPADERM and RIPADERM, emphasizing their high phonetic and conceptual proximity.

Conversely, confusion was excluded in the case of SUMOR and SUMORPLUS (fig.) versus UMORPLUS, where the semantic construction and figurative elements were found sufficient to differentiate the marks. Furthermore, courts have reinforced protection for well-known trade marks, such as ruling FROBENACTIV infringed the established brand BENACTIV, and finding KOKI (with functional suffixes) interfering with the renowned OKI mark. These decisions confirm that even weak pharmaceutical marks cannot encroach on the sphere of well-established signs.

Administrative Proceedings at the IPTO

At the Italian Patent and Trademark Office (IPTO), administrative practice tends to adopt a more protective attitude toward trade mark owners, often recognizing a risk of confusion even where descriptive elements have been modified.

The Office found confusingly similar the marks ENTEROSGEL and ENTEROSAL, IMMUNIX (fig.) and IMMUNID, RIGENASE (fig.) and RIGENEA (fig.), ANSIOLIN and ANSIOSIL (fig.), and upheld the opposition, based on the trade mark FOLISID, against the application for FOLI-SEL (fig.).

Nonetheless, the Board of Appeal (BoA) has overturned several first-instance decisions. In the case of ENZITIME v ENZITASI, Judgment No. 42/24 of 07-06-2024, the BoA held that the prefix ENZI is descriptive 'and that the addition ... of the term TASI by the appellant is capable of creating for the consumer adequate differentiation from the term TIME contained in the opponent's mark'.

In Decision No. 91/2024 of 27-09-2024 ENTERISOL v ENTEROSAN, the Board of Appeal recognized the descriptiveness of the prefix ENTER and the distinguishing effect of the suffixes ISOL / OSAN for the respective signs.

Previously, in a decision from 2022 involving the marks VITREOSAN v VITREO360, it was held that the suffix 360 in VITREO360 was sufficient to differentiate the later mark given the descriptiveness of the term VITREO.

These reversals demonstrate that appeal proceedings remain a meaningful route for applicants or owners facing strict first-instance assessments.

Counterfeit Medicines and Illicit Distribution Channels

Beyond trade mark conflicts, the sector faces the escalating challenge of counterfeit and illegal medicines - an issue with severe implications for patient safety and for the integrity of pharmaceutical markets. Counterfeit products may contain no active ingredient, incorrect substances, inaccurate dosages, or genuine ingredients packaged in falsified materials. Such products, often distributed through unregulated online channels or informal networks, pose substantial risks to public health.

In industrialized countries, counterfeit circulation is particularly prevalent within 'lifestyle drugs': products tied to performance enhancement, sexual health, weight loss, aesthetic treatments, and

other non-therapeutic uses. Increased consumer familiarity with online purchasing and reliance on unofficial information sources further facilitates market infiltration by illegal operators.

The Italian Framework: Strengths and Emerging Obligations

According to recent data from AIFA, Italy's legal supply chain is considered highly secure due to strict traceability mechanisms and the coordinated activities of a dedicated national task force involving AIFA, the Ministry of Health, law-enforcement bodies, the National Institute of Health, and the Customs Agency. Most violations occur outside the official distribution chain, particularly through online sales and parallel informal markets such as gyms and aesthetic centres. There are hundreds of thousands of cases of seizures each year, mostly related to online sales. However, the national landscape has distinguished itself over time in the fight against such offences thanks to the adoption of effective initiatives at both regulatory and operational levels, with an interdisciplinary and coordinated approach, necessarily also on an international scale.

A key development for the Italian system is the implementation of the EU Falsified Medicines Directive (2011/62/EU) and the related Delegated Regulation (EU) 2016/161. Legislative Decree No. 10 of 6 February 2025, in force since 8 February 2025, introduces mandatory safety features on pharmaceutical packaging, including unique identifiers and anti-tampering devices. This transition requires strong coordination among authorities, manufacturers, distributors, and healthcare professionals, and will further enhance transparency and supply-chain security.

Conclusion

For pharmaceutical companies, trademark strategy and anti-counterfeiting efforts are increasingly interconnected priorities. When adopting evocative marks, companies must anticipate potential interference risks and consider recent jurisprudential developments on weak-mark protection. At the same time, they must strengthen supply-chain controls and invest in advanced serialization and authentication technologies. Consumer education and institutional collaboration remain essential tools in limiting illicit distribution channels. By integrating robust branding strategies with effective anti-counterfeiting measures, the industry can simultaneously safeguard its intellectual property and protect public health.

Beyond Classification: trade mark Infringement in the MEDILICE Case, India

Mr. Ranjan Narula and Mr. Mohandas Konnanath, RNA

In a trade mark dispute concerning the mark MEDILICE used for anti-lice shampoo brought by Wings Pharmaceuticals (the plaintiff) and the defendant's use of the mark MEDILICE LICE KILLER for anti-lice ayurvedic (herbal) hair oil, the court ruled in favour of the plaintiff. This note outlines the Appeal filed by the defendant before the Division Bench (two judge Bench) of the Delhi High Court against the decree / permanent injunction order passed by the Commercial Court (at Tis Hazari, District Court). The High Court examined the impact of prior use by the plaintiff, prosecution history of the trade mark registration in favour of the plaintiff, acquiescence argument raised by the defendant, and punitive damages awarded by the Commercial Court. While affirming the findings on infringement and passing off, the Division Bench modified the damages, substituting punitive damages with notional compensation.

The plaintiff, Wings Pharmaceuticals claimed adoption of the mark MEDILICE in 1998 for anti-lice shampoo containing permethrin and secured registration in Class 3 in 2014.

In 2020, the plaintiff discovered the defendant's use of the mark MEDILICE LICE KILLER for anti-lice oil and instituted a suit alleging infringement, passing off, and seeking rendition of accounts. The defendant, M/s Rapple Healthcare asserted prior use since March 2000, relying on affidavits of use filed before the Trademarks Registry and its own trade mark registrations in different classes. Both parties lead evidence through witnesses and upon conclusion of the trial, the Commercial Court held that the defendant had infringed the plaintiff's registered mark MEDILICE.

The Commercial Court ruled that:

- Plaintiff had established valid ownership, assignment, and continuous use since 2004, while the defendant failed to prove prior use.
- Both parties were marketing similar anti-lice products through the same trade channels; therefore, a clear likelihood of confusion, constituting infringement and passing off was established.
- An adverse inference has to be drawn owing to the defendant's failure to produce financial records despite court directions. The Court on that basis awarded ₹10,00,000 (approx. USD \$10,700) as punitive damages in lieu of rendition of accounts.

Issues Before the Division Bench

The following issues came up for consideration in the appeal:

- Whether the defendant infringed the plaintiff's registered trade mark MEDILICE by use of MEDILICE LICE KILLER.
- Whether the defendant was passing off

its goods as those of the plaintiff by use of the impugned mark and in defence the defendant proved prior and continuous use.

- Whether the suit / relief was barred due to alleged delay and acquiescence.
- Whether the plaintiff was entitled to rendition of accounts / damages and whether in the facts of this case punitive damages could be awarded.

The High Court's Ruling Deceptive Similarity and Dominant Feature Doctrine

- The Court reaffirmed that in composite marks, the dominant feature is decisive. The word MEDILICE constituted the essential component of both marks. The suffix LICE KILLER was descriptive and insufficient to distinguish the marks.
- Applying the test of the average consumer with imperfect recollection, the Court held that the rival marks were deceptively similar.
- Importantly, the Court emphasized that where goods relate to medicinal or therapeutic treatment, a stricter standard of scrutiny applies due to potential public health implications.

Registration in Different Classes: Not a Complete Defence

- Although both parties held registrations in different classes, the Court clarified that trade mark protection is confined to the goods for which the mark is registered. However, classification does not determine infringement where goods are allied and cognate.
- Anti-lice shampoo and anti-lice oil served the same therapeutic purpose, targeted the same consumer base, and were sold through identical over-the-counter trade channels. The Court therefore rejected the defendant's reliance on its Class 16 registration.

Prior Use: Marketplace Evidence is Essential

The defendant relied on the following to substantiate prior use:

- Trade mark applications
- User affidavits
- Manufacturing licences

The Court held that the above documents, without proof of actual commercial sales, do not establish continuous and bona fide use in the marketplace. On the other hand, the plaintiff produced documented sales figures and invoices demonstrating continuous use from 2004 onwards evidencing prior use.

Prosecution History Estoppel

The defendant argued that the plaintiff was bound by earlier replies to examination reports stating that the marks were distinct.

- The Court rejected this plea, holding:
 - Replies to examination reports are not conclusive admissions.
 - Deceptive similarity is a question of

law to be determined by the Court.

- Statements made before the Registrar do not automatically act as estoppel in infringement proceedings. The Court thus declined to extend prosecution history estoppel beyond its limited evidentiary value.

Delay and Acquiescence

- On the issue of delay, the defendant contended that the plaintiff had knowledge of its mark since 2001 when it was cited in examination proceedings.
- The court observed that citation of a mark in an examination report does not establish knowledge of actual commercial use. Since the plaintiff acted promptly upon discovering market presence in 2020, the plea of acquiescence failed.
- The Court clarified that acquiescence requires positive encouragement or conduct indicating acceptance. Mere delay or silence is insufficient.

Passing Off Established

The Court upheld the finding of passing off on the classic trinity:

- Goodwill established through long-standing sales and reputation.
- Use of a nearly identical mark for the same purpose amounts to misrepresentation.
- Likelihood of diversion of trade and injury to goodwill entitles the plaintiff to damages.

Given the identity of purpose and trade channels, the likelihood of confusion was clear.

Punitive Damages: Judicial Restraint Emphasized

The Commercial Court had awarded ₹10,00,000 as punitive damages, drawing an adverse inference from the defendant's failure to produce financial records.

The Division Bench held that:

- Punitive damages are exceptional and require proof of wilful, blatant misconduct.
- This was a private commercial dispute without evidence of quantified loss or aggravated conduct.
- The court ruled that while the adverse inference was justified, it did not warrant exemplary damages.

Accordingly, the Court set aside the punitive damages and granted nominal damages of ₹3,00,000 (approx. USD \$3,200) to balance deterrence and equity.

Key Takeaways

- Dominant feature analysis governs deceptive similarity.
- Classification of goods does not limit infringement where products are allied and cognate.
- Prior use must be established through marketplace evidence.
- Prosecution history does not create automatic estoppel.
- Acquiescence requires positive conduct, not mere delay.
- Punitive damages must be awarded cautiously and sparingly.

PROFILE: Maximilian Kammler

Max studied law at the University of Bonn and took his state exams in Cologne. In 2000, he was admitted to the bar and started his career as a criminal defense lawyer. As of 2002, he advised and represented clients from German pharmaceutical industry, physicians, and veterinarians with a focus on rules of professional conduct, health insurance, unfair competition and Intellectual Property. He joined Boehringer Ingelheim as Senior Trade Mark Lawyer in 2009, promoted to Group Head 'Trade Mark Law' and finally 'Head of Trade Marks' for their Trade Mark, Domain and Design portfolio in 2014.



Where were you brought up and educated?

I grew up near to Germany's former capital Bonn, in a very small village with a population of only 300 inhabitants before I studied law at the University of Bonn and finished my preparatory services at the higher regional court in Cologne. In addition, I had the privilege of living 3 years in South Korea (from 1985 to 1987), a time when that tiger state was about to take off, when there was no internet and when it took months for mail and parcels to be shipped between Germany and South Korea in overseas containers.

How did you become involved in trade marks?

By chance. After the second state exam and my admission to the bar, I started working in a law firm in Cologne, mainly focussing on white-collar crime cases and pharmaceutical- and health insurance law. When one of the associates left the firm, I was ordered to take over her department, which mainly consisted of IP- and unfair competition cases and a small trade mark portfolio of some 300 registrations. What started off as the youngest lawyer in the firm being instructed to handle the cases nobody else wanted to do, turned out to be my fortune. I loved it.

What would you have done if you hadn't become involved in intellectual property?

I would probably still be a lawyer. I enjoy advising people in my area of expertise and helping others to navigate.

Which three words would you use to describe yourself?

Diligent. Fair. Foresighted. I hope the people around me agree.

Complete the sentence: I wish . . .

... I had learned more languages.

What was (were) your best subject(s) at school?

Biology – which still helps me a lot in my current role.

What was your worst experience in the world of work?

While still in private practice, I once defended a veterinarian who was charged

with having neglected professional standards in the way he had organized his medicine cabinet and dispensing of drugs. The accusations originated from competing veterinarians. The hearing in court took several days. It was frightening to see how a judge who had no in-depth knowledge of the legal framework was willing to sentence the veterinarian by basically following the accusations and ignoring the arguments of the defence. The criminal conviction was lifted in second instance. The case still reminds me how important the right to appeal a decision is.

What was your biggest work or career mistake and what did you learn from it?

As a young lawyer, I participated in what we would today call a spin-off and I entered into long-term commitments assuming that that was my only option. I disregarded my gut feeling and ended up being bound to people that I should have known better not to trust. That's when I learned that you can't change people and that a maniac in a small team is even harder to control than in a bigger group.

Complete the sentence: I'm no good at ...

... drawing or painting. And I'm afraid that will never change.

What is the best thing about your job?

I very much enjoy working in a super specialized area and interacting with many different cultures and countries.

What does all your money get spent on?

I try to enjoy life. And I'm not picky. Maybe a bottle of wine, my boat on the Rhine river, a pair of Italian shoes or a sunset at the beach.

What is your biggest regret?

I regret that I stopped playing the guitar many years ago. I thought I didn't have the time. But the truth is, I didn't dare to take the time.

What is the most surprising thing that ever happened to you?

Sitting next to a woman in a plane who married me two years later.

What is the best age to be?

I'm still tempted to say the current one. Knock on wood that my health allows me to repeat that statement for many years to come.

What is your philosophy in a nutshell?

You don't always need to be right. Sometimes, it is sufficient if you know better.

What is the toughest thing about your job?

I guess that is constantly changing with my development. When I moved from private practice to being an inhouse counsel, I had to learn that people tend to disregard your advice because they don't have to pay for it. Today, I find it rather challenging to juggle all the different hats that we need to wear in a modern working environment.

Who was your mentor or role model?

I owe a lot to Jürgen Römhild who gave me the chance to transfer my general trade mark knowledge to the very specific world of pharmaceutical trade marks and supported me while I learned to navigate in the complex structure of a multinational pharmaceutical company.

What is your all-time favourite film?

Certainly the Indiana Jones quadrilogy. Steven Spielberg, George Lucas and Harrison Ford at their best.

Which one person would you invite to dinner (other than a family member or relative)?

If he was still alive: Germany's former chancellor Helmut Schmidt. One of the most precise thinkers and analysts with a wealth of experience and foresight. I would open a bottle of wine and listen to his views. I'm afraid he wouldn't follow the invitation. Smoking is not allowed in my kitchen, and he was probably the last person to be allowed to smoke publicly on TV during an interview. He simply wouldn't attend otherwise.